IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MINNESOTA

In re MIRAPEX PRODUCTS LIABILITY LITIGATION	MDL No.: 07-1836 (JMR/FLN)
This document relates to	
ROBERT ZWAYER, et al., GARY E. CHARBONNEAU, et al., HYLTON DODD, Plaintiffs, vs. BOEHRINGER INGELHEIM PHARMACEUTICAL, INC., a Delaware corporation, PFIZER INC., a Delaware corporation, PHARMACIA CORPORATION, a Delaware corporation, and PHARMACIA & UPJOHN COMPANY LLC, Defendants.	Civil No. 06-cv-00874 (JMR/FLN) Civil No. 06-cv-01215 (JMR/FLN) Civil No. 06-cv-02145 (JMR/FLN) **MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS' JOINT MOTION FOR SUMMARY JUDGMENT OR, ALTERNATIVELY, FOR PARTIAL SUMMARY JUDGMENT**

I. INTRODUCTION

Plaintiffs Gary Charbonneau, Hylton Dodd, and Robert Zwayer each allege that the prescription drug that successfully treated their Parkinson's disease, Mirapex®, caused them to gamble – not just once, but pathologically over years, resulting in hundreds of thousands of dollars in losses. Plaintiffs' attempt to recover gambling losses (and so-called "lost opportunity" damages) as a result of the use of a prescription medicine is unprecedented. Moreover, the prescribing information on the label that defendants provided to prescribing physicians tracked the prevailing scientific knowledge at the time and, in each instance, received FDA approval, making these cases particularly inappropriate for establishing such a precedent.

First, the remoteness of these claimed losses from the alleged failure to warn, the duty of a plaintiff to mitigate damages, and the significant public policy against holding defendants liable for gambling losses in any context make gambling losses unrecoverable here as a matter of law. Looking at timing alone, Charbonneau did not allegedly start gambling until more than four years after he started on Mirapex; Dodd not until three to five years later; and Zwayer not for nearly one year.

Second, the "lost opportunity" costs that plaintiffs claim as damages are just prejudgment interest in disguise. Prejudgment interest – the lost opportunity to use money – is not recoverable as damages. It is awarded, if at all, by the Court post-verdict.

Third, plaintiff's evidence is insufficient to prove that Mirapex causes pathological gambling. There is not a single epidemiological study showing such a cause-and-effect relationship, and the anecdotal case reports and other data on which plaintiffs rely are not sufficient to establish causation in this Circuit.

Fourth, beginning in November 2004, the Mirapex label specifically mentioned that there had been reports of pathological gambling. This has the effect of cutting off any failure-to-warn claim from that point forward as a matter of law.

Finally, Zwayer's and Dodd's claims fail under the learned intermediary rule. Dodd's claims fail for the additional reason that Texas law presumes that FDA-approved prescription drug warnings are adequate as a matter of law, and any attempt to rebut that presumption with evidence of "fraud on the FDA" is preempted.

For these reasons and others set forth below, Pfizer and BIPI are entitled to summary judgment.

II. FACTUAL BACKGROUND

A. Parkinson's Disease Is A Debilitating Disease That Affects Millions Of People Worldwide And For Which Mirapex Is A Leading Treatment

Parkinson's disease ("PD") is a debilitating neurodegenerative disease resulting in progressive physical disability and affecting approximately one million people in North America alone. (Exh.C at 12-13; Exh.B at 4-5 (all "Exh." citations refer to exhibits to Declaration of Mildred Segura).) Since the 1970's, PD has been treated primarily with the prescription medication levodopa – the metabolic precursor to dopamine – which is metabolized by nerve cells in the brain to create dopamine. (Exh.B at 4-5; Exh.C at 12.)

Dopamine agonists such as Mirapex are a second class of drugs commonly prescribed for treatment of PD symptoms. Generally, dopamine agonists work by stimulating dopamine receptors, and they have a longer half life than levodopa [Exh.C at

13], which means they are more predictable pharmacokinetically and have improved efficacy. Since the FDA approved Mirapex as safe and effective for treating PD symptoms in 1997, physicians have prescribed it millions of times, and it remains a leading PD treatment.

B. Mirapex is an FDA-Approved Treatment for Parkinson's Disease and Restless Legs Syndrome

1. Development, Testing And Approval Of Mirapex

Mirapex was developed and marketed by BIPI, Pfizer, and Pfizer predecessors. BIPI submitted an Investigational New Drug ("IND") Application to the FDA in 1990 indicating its intent to study Pramipexole, the compound eventually marketed as Mirapex, for treatment of PD. (Exh.D.) In 1993, BIPI transferred the IND to The Upjohn Company ("Upjohn"), which was later acquired by Pharmacia Corporation ("Pharmacia"), and eventually Pfizer. (Exh.E.) The FDA approved Mirapex in July 1997 as a safe and effective treatment for PD. (Exh.H.) On January 1, 2004, Pfizer transferred the New Drug Application ("NDA") for Mirapex to BIPI. (Exh.I.) In November 2006, Mirapex was approved for the safe and effective treatment of Restless Legs Syndrome ("RLS"). (Exh.J.) Since the RLS approval, BIPI has engaged in some direct-to-consumer advertising, but only in connection with RLS and not during any time when the three bellwether plaintiffs were taking Mirapex.

From BIPI's submission of the first IND in 1990 to Upjohn's submission of a complete NDA in December 1995, a total of 49 clinical trials were conducted involving 2,103 patients. (Exh.K at 3351.) Each of these clinical trials and all other steps in Mirapex's development were carried out under the FDA's rigorous NDA process. 21 U.S.C. § 355 (b), (d). The FDA evaluated the animal and clinical trial data, the

proposed labeling and advertising, as well as every other aspect of Mirapex's development and manufacture. (Exhs.H,J.) As a condition of approval, defendants were required to comply with the FDA-mandated manufacturing processes and labeling. 21 U.S.C. 355(e). Even today, defendants' marketing and distribution remains subject to FDA oversight and authority, including the submission of adverse event reports and annual safety reports. 21 U.S.C. § 331 (a), (b), (k); 21 U.S.C. § 332; 21 U.S.C. § 334(a); 21 U.S.C. §§ 352(2), (f), (j), 355(a) and 321(n); 21 C.F.R. 314.70(b)(c).

2. FDA Labeling And Reporting Requirements

Under FDA regulations, the "applicant," *i.e.*, the holder of the NDA, is responsible for monitoring and reporting serious, unexpected adverse drug experiences to the FDA. 21 C.F.R. § 314.80(b). Once an NDA has been approved, the applicant shall submit a supplement to the FDA advising of any changes to the drug label that add or strengthen warnings, and the supplement shall fully describe such changes. *Id.* at § 314.70(c)(2).

FDA labeling and reporting obligations shift when an NDA owner transfers the NDA, as Pfizer did to BIPI in 2004. 21 C.F.R. § 314.72. Accordingly, until January 1, 2004, Pfizer was the "applicant" responsible for the Mirapex label and reporting adverse events, and BIPI was the "applicant" thereafter. Although plaintiffs throughout this litigation have attempted to blur the distinction between the "defendants," it is important to distinguish between Pfizer and BIPI in these failure-to-warn cases since only one was subject to FDA labeling requirements at any given time.

3. Mirapex Labeling

In November 2004, BIPI, as the holder of the NDA, submitted a "Changes Being Effected" notice to the FDA, informing it of a voluntary change to the label regarding post-marketing anecdotal reports of obsessive-compulsive disorder, pathological gambling, and hypersexuality with dopamine agonist therapy. (Exh.L.) The Mirapex prescribing information changed immediately upon submission of the change notice in November 2004 and was memorialized in print in March 2005. (Exh.M at 192995-96.) In February 2006, BIPI again voluntarily supplemented the labeling for Mirapex to include information regarding postmarketing reports of impulse control disorder, obsessive compulsive disorder, pathological gambling, and hypersexuality in the "Precautions" section of the package insert. (Exhs.N,O at 1859135.)

Mirapex label changes have never been under FDA mandate – all changes have been voluntary. Moreover, the FDA's approval of Mirapex has never been suspended, withdrawn or revoked. In October 2006, the FDA further reviewed available medical literature and post-marketing reports related to urges to gamble, increased sexual urges, and other intense urges in patients using Mirapex. Based on all information available at that time, the FDA determined there was no proof of a cause-and-effect relationship. (Exh.P.) As the FDA stated:

> [W]e recently completed a review of post marketing reports and the published medical literature regarding development of intense urges to gamble, increased sexual urges and other intense urges in patients using medications for PD. . . . ***Although we feel that the available information does not constitute proof of a cause and effect relationship***, we believe the evidence to be sufficiently strong to warrant that patients be informed about the potential for experiencing intense urges when using these medications.

(*Id.* (emphasis added))

C. The Plaintiffs

1. Hylton Dodd

Hylton Dodd is a 75-year-old resident of Wichita Falls, Texas. (Exh.Q No. 1.) Dodd was diagnosed with PD in August 2000 by Dr. Stephen Farmer, and he took Mirapex from October 2000 through November 2005. (*Id.* at Nos. 1, 6, 8.)

According to Dodd's interrogatory responses, his compulsive gambling began in December 2003, five months after his second wife died, and more than three years after he started taking Mirapex. (*Id.*) At deposition, however, ***Dodd revised the date to May 2004, nearly five years after he had first taken the drug***. (Exh.S at 29, 81, 95, 96.) In addition to pathological gambling, Dodd alleges that Mirapex caused him to shop, give money away to friends and acquaintances, and consort with women of low moral character. (Exh.S at 29,71; Exh.Q No. 12.)

After reading a July 2005 newspaper article about Mirapex and alleged compulsive behavior [Exh.Q No. 16; Exh.S at 79, 103], Dodd raised the purported connection with his prescribing physician, who told him to continue taking Mirapex because there was not enough known about the association for him to stop. (Exh.S at 105.) Nonetheless, Dodd conducted further Internet research into the issue, and as a result, cut back on the time he spent at the casino and on the money he spent shopping, although he continued to take the drug. (*Id.* at 106-07.)

In November or December 2005, despite his doctor's instruction, Dodd decided to stop taking Mirapex. (*Id.* at 108.) He still gambles at least once per week playing blackjack and, occasionally, the slots. (*Id.* at 98, 168.)

2. Gary Charbonneau

Gary Charbonneau is a 67-year-old resident of Milwaukee who was diagnosed with PD on or about May 14, 1996, by Dr. Denis C. Nathan. He took Mirapex to treat his PD from December 1997 through November 2005. (Exh.V Nos. 1, 6, 8; Exh.W at 24-25.) He claims that Mirapex caused him to begin gambling in April 2002, ***more than four years after he started taking the drug***.[1] (Exh.V No. 12; Exh.W at 89; Exh.X at 2.) In addition, Charbonneau played Internet poker on 26 occasions between November 2004 and October 2005. (Exh.Z at 35 (final page).)

Charbonneau claims that he first learned about a possible connection between Mirapex and pathological gambling in July 2005 "as a result of the study that was published by the Mayo Clinic," and when he "saw a program on *Good Morning America*." He nonetheless continued to take Mirapex and to gamble. He heard again about a possible association between Mirapex and gambling at a Gamblers Anonymous meeting in September 2005. He took Mirapex for another two weeks. (Exh.V No. 16; ¶25; Exh.W at 89, 105-06, 251-52, 106-07, 108, 25-53.)

3. Robert Zwayer

Robert Zwayer is a 68-year-old resident of Lakeland, Florida who was diagnosed with Parkinson's disease in October of 2003. He took Mirapex from October 2003 to August 2005. (Exh.BB Nos. 1, 2, 6, 8.) Zwayer claims he gambled compulsively from

[1] Although Charbonneau claims Mirapex caused him to start gambling in 2002, he has admitted that he began buying lottery tickets in his fifties, began gambling at racetracks beginning in his forties, and had been playing card games for money on a long-standing basis. (Exh.Y at 22.) He also engaged in "day trading" in the 1990s, a risky and fast-paced investment method that involves trading in securities and holding positions for short periods of time, sometimes just minutes. (Exh.X at 7.)

about August or September 2004 – nearly a year after he started taking Mirapex – until about September 2005. (*Id.* Nos. 12, 18; Exh.CC at 114, 165-66.) His compulsive gambling coincided with the opening of a casino just minutes from his home. (Exh.DD.) In an April 2005 letter to his wife, Zwayer wrote that he thought his gambling may have been attributable to medication, but he did not tell his doctors and continued taking Mirapex. (Exh.CC at 159-60.)

D. Plaintiffs' Complaints Allege Mainly That BIPI And Pfizer Failed To Warn Adequately In Connection With Mirapex

Plaintiffs filed virtually identical complaints alleging that Mirapex caused them to develop "a pathological gambling addiction." (Dodd, Charbonneau, and Zwayer Compls. ¶1.) The crux of plaintiffs' complaints is that defendants knew or should have known that Mirapex caused pathological gambling, but failed to warn plaintiffs, physicians and the general public of that alleged risk. (*Id.* ¶¶ 16, 26, 27, 31, 35, 41, 42, 46, 49.) Specifically, plaintiffs bring causes of action for: **(1) Strict Liability**, alleging that defendants failed to provide adequate warnings that "Mirapex causes compulsive behavior," and that Mirapex was defectively designed and/or that the Mirapex plaintiffs ingested was defectively manufactured (*id.* ¶27); **(2) Breach of Express Warranty**, alleging that plaintiffs were injured because defendants did not tell them that Mirapex can cause pathological gambling (*id.* ¶31); **(3) Breach of Implied Warranty**, alleging that defendants impliedly warranted that Mirapex would not cause pathological gambling (*id.* ¶34); **(4) Negligence**, alleging that "Defendants had a duty to warn plaintiff, his physicians . . ." of the alleged risk of pathological gambling (*id.* ¶40); **(5) Negligence Per Se**, alleging Mirapex was inadequately labeled under federal law (*id.* ¶46); and **(6) Negligent Misrepresentation**, alleging that defendants failed to adequately communicate information regarding Mirapex to plaintiffs and their physicians (*id.* ¶49). In addition,

Zwayer's and Charbonneau's spouses have asserted loss of consortium claims. (Zwayer and Charbonneau Compls. ¶57.) On January 9, 2008, plaintiffs added a prayer for "punitive damages and other exemplary relief." (Amended Compls. at 17.)

III. LEGAL ARGUMENT

A. The Summary Judgment Standard And Choice Of Substantive Law

Summary disposition is appropriate where the summary judgment record "show[s] that there is no genuine dispute of material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. Proc. 56(c). "An issue of fact is genuine when 'a reasonable jury could return a verdict for the nonmoving party' on the question." *Woods v. DaimlerChrysler Corp.*, 409 F.3d 984, 990 (8th Cir. 2005) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). A fact is material when it "might affect the outcome of the suit under the governing law." *Anderson*, 477 U.S. at 248.

Once the movant has demonstrated the lack of a genuine issue of material fact, the opponent must present "specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e); *see also Hartnagel v. Norman*, 953 F.2d 394, 395 (8th Cir. 1992) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)); *Baum v. Helget Gas Prods., Inc.*, 440 F.3d 1019, 1022 (8th Cir. 2006).

As Magistrate Judge Noel concluded in his November 26, 2007 Order, the substantive law of each plaintiff's home state applies to his or her case. (11/26/07 Order at 6.) Accordingly, Dodd's claims are governed by Texas law; Charbonneau's claims are governed by Wisconsin law; and Zwayer's claims are governed by Florida law.

B. Plaintiffs' Alleged Gambling Losses Are Not Recoverable

Although these are product liability, personal injury lawsuits, plaintiffs do not allege any physical harm. Rather, their claimed damages are their alleged gambling losses and purported "lost opportunities" associated with those losses. Yet, there simply is no authority for the Court to award such damages in a product liability action involving a prescription drug. *See Robinson v. United States*, 175 F. Supp. 2d 1215, 1233 (E.D. Cal. 2001) (granting partial summary judgment, ruling that the plaintiff could not recover emotional distress damages, and determining the valuation for the plaintiff's lost personal property); *Bryant v. United States*, 126 F. Supp. 2d 1227 (D. Ariz. 2000) (granting partial summary judgment, ruling that the plaintiff's personal injury damages were limited to a statutory amount).

A product manufacturer can be subject to liability for "physical harm . . . caused to the ultimate user or consumer, or to his property." Restatement (Second) of Torts § 402A. Damages arising out of such product liability injuries typically include compensation for pain and suffering, emotional distress, permanent injury, loss of enjoyment of life, medical expenses, lost wages, and impairment of earning capacity. *See* 41A Fla. Jur. 2d *Products Liability* § 80 (2007) (Under Florida law, "[w]here the plaintiff was injured as the result of a product, the elements of damages . . . are bodily injury, pain and suffering, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, aggravation of an existing disease or defect, loss of earning capacity, hospital and medical expenses."); Tex. Civ. Prac. & Rem. Code § 41001(12) (under Texas law (Dodd), "[n]oneconomic damages" means damages awarded for the purpose of compensating a claimant for physical pain and suffering, mental or emotional pain or anguish, loss of consortium, physical impairment, and loss of enjoyment of life); *Rennick v. Fruehauf*, 82 Wis. 2d 793, 803 (Wis. 1978) (applying Wisconsin law (Charbonneau) in

products liability action, court affirmed emotional distress damages award and reduction of damages award for past economic loss, future pain, suffering, and future loss of earnings.); *Fraysier v. United States*, 566 F. Supp. 1085, 1090 (S.D. Fla. 1983) (applying Florida law (Zwayer)), *aff'd*, 766 F.2d 478 (11th Cir. 1985).

Gambling losses do not fall within any of these recognized categories of product liability damages. Indeed, they do not even qualify as product liability economic injury damages. The law does not hold a defendant "liable for every conceivable consequence that might somehow be causally related to its conduct." *See Port Authority v. Arcardian Corp.*, 189 F.3d 305, 318 (3d Cir. 1999). Thus, as a matter of law and consistent with sound public policy, the Court should not stretch the law to permit product liability plaintiffs to recover theoretically limitless gambling losses.

In drawing lines limiting liability, courts have relied on a variety of concepts, perhaps the most important of which is legal or proximate causation. *See Union Pump Co. v. Allbritton*, 898 S.W. 2d 773, 775 (Tex. 1995) ("[t]he doctrine of 'proximate cause' is employed to determine and fix this line and 'is the result of an effort by the courts to . . . apply a practical test, the test of common experience, to human conduct when determining legal rights and legal liability . . ."). As the leading treatise on tort law has suggested:

> "Proximate cause" . . . is merely the limitation which the courts have placed upon the actor's responsibility for the consequences of the action's conduct . . . . Some boundaries must be set to liability for the consequences of any act, upon the basis of some social idea of justice or policy.
>
> This limitation is to some extent associated with the nature and degree of the connection in fact between the defendant's acts and the events of which the plaintiff complains. Often to greater extent, however, the legal limitation on the scope of liability is associated with policy—with our more or less inadequately expressed ideas of what justice demands, or of what is administratively possible and convenient.

W. Page Keeton, et al., *Prosser and Keeton on the Law of Torts* § 41, at 264 (5th ed. 1984).

Principles of legal or proximate causation raise two main questions: (1) whether the defendant's conduct in fact caused the plaintiff's damages and (2) whether the policy of the law requires the defendant to be legally responsible for the injury, generally a legal question. *See, e.g.*, Prosser and Keeton, *supra*, § 41 ("[i]n many tort law settings, the boundaries of proximate cause are set primarily by policy considerations – not by our often uncertain understandings of physics or 'principles' of social dynamics"); *see also Widell v. Tollefson*, 158 Wis. 2d 674, 682 (1990) (determination of "proximate cause" through evaluation of public policy considerations is a question of law).

As to the first question, the undisputed facts show that the event that actually caused each of the plaintiffs to lose money gambling was the gambling itself. Even assuming that Mirapex does increase urges to gamble in some people – and defendants contest that the science has established that – those increased urges would not cause any monetary losses without gambling opportunities. Even plaintiff's own expert, Dr. Bechara agrees with this common-sense conclusion – he contends that pathological gambling is observed among Parkinson's patients more than other impulsive behaviors because of the availability and nature of gambling opportunities. (Exh.LL at 250-52.)

In fact, the undisputed evidence shows that the three plaintiffs began gambling anywhere from a year to five years after first taking Mirapex and that what proximately caused each plaintiff to gamble was the availability of a gambling outlet. Zwayer provides the best example: his alleged compulsive gambling coincided with a casino opening minutes from his home. (Exh.DD.) The triggering event for Charbonneau was the immediate availability of a shipboard casino while he was on a cruise, four years after

he began his Mirapex therapy. (Exh.W at 92.) Dodd began gambling compulsively more than three years after he started taking Mirapex and after his second wife passed away. (Exh.Q No. 12; Exh.S at 18, 29, 81, 95, 96; Exh.U at 5.) Although he stopped taking Mirapex two years ago, he still gambles regularly. (Exh.S at 98, 168.)

Therefore, in terms of temporal proximity, no reasonable trier of fact could conclude that Mirapex caused Zwayer, Charbonneau or Dodd to begin gambling. Pfizer and BIPI played no part in plaintiffs' gaining access to casinos in which to incur gambling losses. Moreover, the ***losses*** themselves are the proximate result of a multitude of factors with which Pfizer and BIPI have no arguable connection – *e.g.*, plaintiffs' poor game selection, their poor strategy, their gambling history, or even their own bad luck. Only plaintiffs and the casinos in which they gamble have the ability to cause gambling losses.

In addition to lack of factual support, plaintiffs' attempts to recover their alleged gambling losses fail under the second (legal responsibility) prong of the proximate causation analysis. Recovery of gambling losses generally is disfavored, even when gamblers claim to be unable to control their behavior. In *Merrill v. Trump Indiana, Inc.*, 320 F.3d 729, 731 (7th Cir. 2003), the plaintiff identified himself as a compulsive gambler and availed himself of the defendant-casino's self-eviction procedure, but the casino let him back in. After the plaintiff's gambling losses led him to rob two banks, he sued the casino for damages, faulting it for failing to prevent him from gambling. *Id.* at 730-31. In granting summary judgment for the casino, the court held that even if the casino failed to prevent the plaintiff from gambling, the law still did not protect the gambler from "the effects of his own conduct." *Id.* at 733.

The Third Circuit's discussion in *Hakimoglu v. Trump Taj Mahal Assoc.*, 70 F.3d 291 (3d Cir. 1995), is equally instructive. There, the court held that the plaintiff casino patron could not recover damages from the defendant casino for gambling losses allegedly incurred while the plaintiff was intoxicated. *Id.* at 292-93. The court emphasized the difficult problems of proof and causation that would result from the recognition of claims for gambling losses: "enlargement of [the doctrine of dram-shop liability] to casino gambling losses could present almost metaphysical problems of proximate causation, since sober gamblers can play well yet lose big, intoxicated gamblers can still win big, and under the prevailing rules and house odds, 'the house will win and the gamblers will lose' anyway in the typical transaction." *Id.* at 294 (quoting *Hakimoglu v. Trump Taj Mahal Assoc.*, 876 F. Supp. 625, 636 (D.N.J. 1994)).

Courts have been reluctant to allow gamblers a cause of action to recover their gambling losses even where allegations of cheating are concerned. In *Vu v. California Commerce Club, Inc.*, 58 Cal. App. 4th 229, 231-32 (1997), the plaintiffs alleged that a card club failed to prevent, and in some instances participated in, cheating that led to large losses. However, the court granted summary judgment for the club on proximate cause grounds, ruling that there was "no reasonably certain causal link between the club's alleged conduct and their gambling losses." *Id.* at 233. As the court observed, "winning or losing at card games is inherently the product of other factors, namely individual skill and fortune or luck." *Id.*; *see also Kelly v. First Astri Corp.*, 72 Cal. App. 4th 462, 471 (1999) (rejecting a gambling loss claim on ground that "California's strong, long-standing public policy regarding gambling is a broad policy against judicial resolution of civil claims arising out of lawful or unlawful gambling contracts or transactions"); *Logan v. Ameristar Casino Council Bluffs*, 185 F. Supp. 2d 1021, 1025 (S.D. Iowa 2002) (rejected extension of negligence claim to plaintiff claiming gambling losses, even

though defendant-casino knew that he was a compulsive gambler and an alcoholic and encouraged the behavior).

Here, plaintiffs urge recovery of gambling losses that they allegedly sustained because defendants purportedly failed to warn adequately of risks inherent in Mirapex. Plaintiffs can point to no case permitting such a recovery; indeed, as shown above, courts routinely deny recovery for gambling losses.[2] In these Mirapex cases in particular, there are further compelling reasons why this Court should not extend the law to allow the plaintiffs to recover gambling losses.

First, the connection between defendants' alleged failure to warn and plaintiffs' gambling losses is too remote to impose liability. Second, allowing recovery of gambling losses would violate the recognized duty imposed on each plaintiff to mitigate his damages. Third, allowing plaintiffs' gambling loss claims threatens potential liability far out of proportion to defendants' culpability. Fourth, permitting recovery of gambling losses would encourage behavior that is socially undesirable and often illegal. Any of these reasons is alone sufficient to foreclose recovery of gambling losses. Collectively, these reasons compel that result.

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[2] In cases where courts have allowed claims for gambling losses, it has been against casinos – not third parties – and the casino's alleged conduct has been directly and culpably responsible for the losses. *See, e.g., Greate Bay Hotel & Casino v. Tose*, 34 F.3d 1227, 1228-29 (3d Cir. 1994) (permitting gambling loss claim where casino continued to provide the visibly intoxicated plaintiff with additional alcoholic beverages and encouraged him to gamble); *Wynn v. Monterey Club*, 111 Cal. App. 3d 789, 794 (1980) (permitting claim against card club by gambler's spouse where the card club had promised to bar the spouse and refuse to cash her checks, but went ahead and cashed her checks and let her gamble anyway).

1. The Connection Between Defendants' Alleged Failure To Warn And Plaintiffs' Gambling Losses Is Too Remote To Impose Liability

Even according to plaintiffs' version of events, the alleged failure to warn was just the first in a long sequence of events that led them to gamble and eventually to lose large sums of money, sometimes years after starting Mirapex therapy. The remoteness of the claimed losses as compared to the alleged failure to warn, particularly when coupled with defendants' lack of involvement in and control over the numerous intervening events, is reason to conclude that defendants are not liable for those claimed losses.

Kinsman Transit Co. v. City of Buffalo, 388 F.2d 821, 824 (2d Cir. 1968), illustrates the rationale behind denying liability where the alleged damages are too remote. There, the defendants' negligence caused a ship to break loose and collide with another ship, leading both to ram a bridge downstream. The resulting floods delayed the plaintiff's grain shipments, and substitute grain had to be obtained. *Id.* at 822-23. However, the court held that the plaintiff's economic losses were too remote to allow recovery. *Id.*

The court also found the connection between the alleged wrongful conduct and alleged economic losses too tenuous in *Wyatt v. Longoria*, 33 S.W.3d 26, 31-34 (Tex. App. 2000). The defendant in that case allegedly misdiagnosed the plaintiff as having terminal cancer. *Id.* This diagnosis caused the plaintiff to make "ill-advised" property dispositions, which led to financial losses. Although the court had no trouble finding actual causation, the plaintiff could not overcome the proximate cause hurdle. The economic harm she complained of "was not within the type of harm which [the defendant] reasonably should have anticipated." *Id.* at 34. Furthermore, the defendant

had no control over how his patients decided to dispose of their property in anticipation of death. *Id.*

Here, even if plaintiffs could establish general causation, the Court should cut off defendants' potential liability as a matter of law because of the remoteness of plaintiffs' alleged injuries. In nearly every other pharmaceutical product liability case, the drug is alleged to cause harm *with no further intervention*. By contrast, the path from ingestion of Mirapex to alleged gambling losses is attenuated and requires a series of volitional acts by plaintiffs and multiple interventions by third parties. The failure to warn must have resulted in the physician prescribing Mirapex when he or she otherwise would not have done so; the drug must have impaired impulse control; the patient suffering from impaired impulse control must have had an inclination to gamble; the patient must have had access to and sought out a casino; the patient must have had access to money or credit to gamble; the actual level and extent of gambling must have exceeded the patient's typical, pre-Mirapex gambling habits; the Mirapex use must have impaired the ability to alter or stop behavior that was obviously destructive; the patient must have had some combination of lack of skill, bad luck, and unfavorable house odds such that he or she lost money. Because of the numerous intervening steps to get from that alleged impairment to actual losses, plaintiffs' alleged gambling losses are simply too remote from their Mirapex use for the law to permit their recovery.

2. Allowing Plaintiffs To Recover Gambling Losses Would Violate Their Legal Duty To Mitigate Their Damages

It is well settled that in these Mirapex cases, plaintiffs have a duty to mitigate their claimed damages. *See, e.g., Formosa Plastics Corp., USA v. Kajima Int'l, Inc.*, 216 S.W.3d 436, 458-59 (Tex. App. 2006) ("the duty to mitigate arises in both contract and

tort cases"); *Howard v. State Farm Mut. Auto. Liab. Ins. Co.*, 236 N.W.2d 643, 647 (Wis. 1975) ("the general rule does require the damaged party to use reasonable efforts to mitigate the damages"). Indeed, any ruling that "would be inconsistent with the party's legal duty to mitigate their [sic] damages" is a "serious policy reason[]" against such a ruling. *Eastman v. Flor-Ohio, Ltd.*, 744 So.2d 499, 504 (Fla. Dist. Ct. App. 1999).

A ruling that plaintiffs may recover their gambling losses would render the duty to mitigate a nullity. Purely economic losses that a plaintiff can control, like gambling losses, are precisely the types of losses that the law imposes a duty to make reasonable efforts to mitigate. However, the substantial gambling losses that plaintiffs seek to recover are *per se* unreasonable and are the result of a failure even to attempt to mitigate those losses. In light of the legal duty imposed on plaintiffs to mitigate their damages, allowing them to recover those patently unmitigated losses would sanction plaintiffs' obvious breach of that duty. Even worse, in addition to absolving plaintiffs of their duty to mitigate their damages, such a ruling would encourage plaintiffs to continue to gamble with impunity, thereby ***increasing*** their losses. This is but another reason to deny recovery here.

3. Allowing A Claim For Gambling Losses Threatens Potential Liability That Is Out Of Proportion To Defendants' Alleged Culpability

This Court also should reject plaintiffs' gambling loss claims because permitting them would threaten liability out of proportion to defendants' alleged culpability. *See Flint v. O'Connell*, 254 Wis. 2d 772, 784-88 (2002) (rejecting cost-of-upbringing damages against physician despite the "wrongful birth" of a child such liability would be vastly out of proportion to the defendant's culpability); *Thing v. La Chusa*, 48 Cal. 3d 644, 664 (1989) (restricting emotional distress damages to limit liability "out of

proportion to the [defendant's] culpability"); *Stephenson v. Universal Metrics, Inc.*, 251 Wis. 2d 171, 196 (2002) (rejecting wrongful death claim that would place a burden on the defendant disproportionate to culpability).

Here, Pfizer and BIPI sold an FDA-approved medicine that improves the quality of life for millions of patients afflicted with a debilitating neurological disease, and the Mirapex labeling was created in full cooperation with the FDA. To this day, the FDA has not criticized Pfizer or BIPI in connection with the development, marketing, or sale of the drug. Against this conduct, plaintiffs would impose liability that cumulates over time, is the result of plaintiffs' own volitional acts, and is potentially limitless. The imbalance is striking and is reason to deny plaintiffs' gambling loss claims.

4. Permitting The Recovery Of Gambling Losses Would Allow Tort Recoveries To Support Behavior That Is Socially Undesirable And Often Illegal

The plaintiffs' gambling losses resulted from the repeated exercise of irresponsible, self-destructive behavior – even *illegal conduct* in the case of Plaintiff Charbonneau's Internet gambling – that was within their control. It would transgress public policy to provide a form of judicial insurance for losses flowing from this undesirable and sometimes illegal behavior.

As a Florida court recently said, the law "prohibits plaintiffs from recovering damages for their own wrongdoing." *O'Halloran v. PriceWaterhouseCoopers LLP*, No. 2D04-147, 2007 WL 1296027, at *4 (Fla. Ct. App. May 4, 2007); *see also Abbott v. Marker*, 722 N.W.2d 162, 166 (Wis. Ct. App. 2006) ("[N]o court shall aid a party whose claim is based on an illegal or immoral act."). Where the plaintiff has engaged in conduct that is *illegal*, and not merely wrongful or irresponsible, this policy is particularly

pointed. If the illegal act is "inextricably intertwined with the claim and the alleged damages would not have occurred but for the illegal act, the plaintiff is not entitled to recover." *Sharpe v. Turley*, 191 S.W.3d 362, 266 (Tex. Ct. App. 2006); *see also Evans v. Cameron*, 360 N.W.2d 25, 28 (Wis. 1985) (denying relief to plaintiff whose claim arose from her own perjury because, as a matter of public policy, "[n]o court will lend its aide to a [person] who founds his cause of action upon an immoral or illegal act."); *Lee On v. Long*, 234 P.2d 9, 11-12 (Cal. 1951) (plaintiffs denied recovery of property seized during raid of illegal gambling operation because "[i]f the plaintiff cannot open his case without showing that he has broken the law, the court will not assist him"); *Jasper v. Rossman*, 41 N.W.2d 310, 312 (S.D. 1950) (judgment as a matter of law against plaintiff to recover sale price of gambling paraphernalia because "betting and gambling are uniformly held to be contrary to the policy of the law").

All of these Mirapex plaintiffs engaged in wrongful, destructive gambling behavior, and as such, the law should not be stretched to provide them with remedies. **This policy consideration is most crucial in the case of Charbonneau's Internet gambling, which is *illegal* in Wisconsin and elsewhere.** *See* Wis. Stat. §§ 945.01, 945.02 (misdemeanor to "make a bet," where parties agree that one stands to win or lose value dependent upon chance); *id.* at § 954.03 (felony when anyone "[f]or gain, uses a wire communication facility . . . for . . . a wire communication which entitles the recipient to receive money or credit as a result of a bet"); H.R. Rep. No. 108-133, at 5 (2003) ("Internet gambling currently constitutes illegal gambling activity in all 50 states."). The authorities cited above leave no doubt that that civil justice system will *not* aid or indemnify a person whose losses stem from his own illegal behavior.

For all the reasons stated above, this Court should not extend the law to allow plaintiffs to recover gambling losses as product liability damages. Defendants are

entitled to a partial summary judgment ruling that such losses are unrecoverable on all of plaintiffs' claims.

C. Plaintiffs Cannot Recover "Lost Opportunity" Damages Because Those Alleged Damages Are Just Prejudgment Interest By Another Name

Plaintiffs claim tens of thousands of dollars in "lost opportunity" as an element of their alleged damages, which they define as money they would have earned had their gambling losses "been available to [them] to be used for other purposes." (Exh.U at 6 (Dodd, $59,295 of "lost opportunity"); Exh.X at 6 (Charbonneau, $69,936); Exh.FF at 6 (Zwayer, $43,824).) But what plaintiffs call "lost opportunity" is actually prejudgment interest, and it is not recoverable as a matter of law in all three states.

Texas, Florida and Wisconsin all define prejudgment interest as the cost of the loss of use of money. In Texas, for example, prejudgment interest is "additional damages for the loss of use of money due as damages during the period between the accrual of the claim and the date of judgment." *Durham Transp. Co. v. Beettner*, 2001 S.W.3d 859, 876 (Tex. App. 2006). Prejudgment interest in Florida similarly is "to compensate an aggrieved party for the wrongful deprivation of the use of his or her money," and Wisconsin views prejudgment interest as "the value of the use of the money – a value which should be accruing for the benefit of the plaintiff-creditor." *First American Bank & Trust v. Windjammer Time Sharing Resort, Inc.*, 483 So. 2d 732, 739 (Fla. Dist. Ct. App. 1986); *Nelson v. Travelers Ins. Co.*, 102 Wis. 2d 159, 169 (1981).

Importantly, in all three states, prejudgment interest is awarded, if at all, only after the jury renders its verdict, and not as an element of damages. *See, e.g., Durham Transp.*, 201 S.W.3d at 876 (Tex. App. 2006) (holding that prejudgment interest should be

calculated based on the *past damages awarded*); *Argonaut Ins. Co. v. May Plumbing Co.*, 474 So. 2d 212 (Fla. 1985) ("finder of fact should not consider the time-value of money in its consideration of damages" because awarding prejudgment interest is "purely a ministerial duty of the trial judge or clerk of the court to add the appropriate amount of interest to the principal amount of damages awarded in the verdict"); *Tony Spychalla Farms, Inc. v. Hopkins Agricultural Chemical Co.*, 151 Wis. 2d 431, 444 (Wis. Ct. App. 1989) (affirming trial court's refusal to allow recovery for interest payments because the payments constituted prejudgment interest). Florida and Wisconsin generally do not permit the award of prejudgment interest at all in personal injury actions because personal injury claims typically are not liquidated. *See Parker v. Brinson Constr. Co.*, 78 So. 2d 873, 875 (Fla. 1955) ("[I]nterest is not allowed in actions for personal injury."); *D'Huyvetter v. A.O. Smith Harvestore Prods.*, 164 Wis. 2d 306, 324 (Wis. Ct. App. 1991) (prejudgment interest "may be awarded only if the amount of damages is determinable prior to judicial determination").

Here, plaintiffs' claimed "lost opportunity" is prejudgment interest, no matter how they label it. Plaintiffs' damages expert, Mr. Frankenfeld, admits that "lost opportunity" is the cost of the loss of use of money, which is the definition of interest. He has opined that Zwayer would have invested his gambling losses in certificates of deposit and annuities and earned 4.29 percent (Exh.FF at 6.) Dodd purportedly would have earned ***15 percent*** investing in stocks and other securities, and Charbonneau would have earned 7 percent in money market accounts and certificates of deposit (Exhs.U,X at 6.) By identifying the alleged cost of each plaintiff's lost use of money, Mr. Frankenfeld could not have described "interest" any more precisely.

Thus, when seen for what it is, plaintiffs' "lost opportunity" is not recoverable as a matter of law.

D. Plaintiffs Have No Admissible Evidence Showing That Mirapex Use Causes Impulse Control Disorders Such As Pathological Gambling

Because these are personal injury actions involving complex medical issues, plaintiffs must prove causation within a reasonable medical probability, if not a reasonable medical certainty, based upon competent expert testimony. *See Ins. Co. of N. Am. v. Myers*, 411 S.W.2d 710, 713 (Tex. 1966) (cancer issue was a "question of science determinable only from the testimony of expert medical professionals"); *Crovella v. Cochrane*, 102 So. 2d 307, 310 (Fla. Dist. Ct. App. 1958) ("jurors and courts do not know and are not permitted arbitrarily to say what are the proper methods of diagnosing and treating human ailments," which is the proper subject of expert testimony); *Weiss v. United Fire & Cas. Co.*, 541 N.W.2d 753, 751 (Wis. 1995) (expert opinion is required in "many cases involving medicine" because it involves "special knowledge or skill or experience on subjects . . . not within the realm of the ordinary experience of mankind").

As set forth in the defendants' accompanying *Daubert* motion papers, plaintiffs cannot meet their burden of showing through competent scientific evidence within a reasonable medical probability that Mirapex causes pathological gambling. Plaintiffs have no admissible expert testimony that Mirapex causes pathological gambling because there is no reliable scientific basis to support such an opinion. As defendants' experts have confirmed, *there is no epidemiological data – including even a single randomized prospective controlled study – showing that Mirapex is a medical cause of impulse control disorders.*

Plaintiffs will no doubt emphasize that defendants' experts have acknowledged the possibility that Mirapex bears an association with pathological gambling through its effects on the dopamine system in the brain. But acknowledging a ***possibility*** of an

association is different from acknowledging that Mirapex use ***actually causes*** pathological gambling to a reasonable degree of medical certainty. *See Black v. Food Lion, Inc.*, 171 F.3d 308, 310 (5th Cir. 1999) (applying Texas law; plaintiff must prove causation "to a reasonable degree of medical certainty," not just a possibility); *Purina Mill, Inc. v. Odell*, 948 S.W.2d 927, 938 (Tex. App. 1997) ("[c]ausation must be based on a reasonable probability, rather than a mere possibility."); *Michalski v. Wagner*, 9 Wis. 2d 22, 27 (1960) (plaintiff must establish a "reasonable probability and not [a] mere possibility" of medical causation); *Merco Distrib. Corp. v. Commercial Police Alarm Co.*, 84 Wis. 2d at 460 (a "mere possibility of such causation is not enough" to submit case to a jury); *Greene v. Flewelling*, 366 So. 2d 777, 781 (Fla. Dist. Ct. App. 1978) ("[i]t has long been held that a possibility of causation is not sufficient to allow a claimant to recover."); *Murphy v. Sarasota Ostrich Farm/Ranch, Inc.*, 875 So. 2d 767, 769 (Fla. Dist. Ct. App. 2004) ("[a] mere possibility of such causation is not enough"); *see also Sorensen v. Shaklee Corp.*, 31 F.3d 638, 643 n.8 (8th Cir. 1994) ("The goal of epidemiologic investigation is to identify and establish the causes of human diseases, yet such studies may only report an association between an injury or disease and a specific exposure, which is not necessarily one of cause and effect."); *Glastetter v. Novartis Pharmaceuticals Corp.*, 252 F.3d 986, 990 (8th Cir. 2001) (despite case reports demonstrating a temporal association, "that association [was] not scientifically valid proof of causation").

Plaintiffs did not disclose an expert on epidemiology, and as explained fully in defendants' accompanying *Daubert* motions, the case reports and case studies on which they rely are not sufficient to support a finding of general medical causation. While randomized prospective controlled trials provide the most reliable form of statistical evidence related to cause and effect, anecdotal case reports provide the weakest, since the absence of a control group, limited sample size, and potential bias means that other

causes, including chance, cannot be eliminated. *Glastetter v. Novartis Pharmaceuticals Corp.*, 107 F. Supp. 2d 1015, 1030 (E.D. Mo. 2000); *see also Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 n.5 (8th Cir. 2000) ("Case reports are generally not considered reliable evidence of causation.").

Thus, as defense expert Dr. Kieburtz concluded, "[t]he 200 or so cases of pathologic gambling reported in the literature . . . raise the possibility of an ***association*** with dopamine agonist use but this is very different than a causal connection . . . . Further data from case control studies . . . , cohort or randomized trial databases are needed to establish whether there is indeed an association between dopamine agonist use and pathologic gambling. Causation has not been established." (Exh.B at 22 (emphasis added).) The absence of admissible scientific evidence establishing that Mirapex causes impulse control disorders is fatal to all of plaintiffs' claims, as each includes causation as an essential element. For this reason alone, BIPI and Pfizer are entitled to summary judgment.

E. Plaintiffs' Claims Arising After November 2004 Fail Because The Mirapex Prescribing Information Expressly Addressed Pathological Gambling

Plaintiffs' failure-to-warn claims also fail after November 2004, because the Mirapex labeling specifically addressed pathological gambling from that time forward. *See Upjohn Co. v. MacMurdo*, 562 So. 2d 680, 683 (Fla. 1990) (pharmaceutical warnings sufficient as a matter of law in case alleging menstrual bleeding where drug's package insert addressed "'breakthrough bleeding' and 'change in the menstrual flow'."); *Brumley v. Pfizer, Inc.*, 149 F. Supp. 2d 305, 309-10 (applying Texas law, "if a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law"; where drug warning specifically addressed cardiac risks, warnings were

adequate as a matter of law in case alleging cardiac complications); *Mohr v. St. Paul Fire & Marine Ins. Co.*, 674 N.W.2d 576, 589 (Wis. Ct. App. 2003) (manufacturer's warnings must be adequate and appropriate under the circumstances).

Here, plaintiffs allege that they suffered compulsive behaviors, mainly pathological gambling. BIPI supplemented the Mirapex prescribing information in November 2004 to address that exact risk. Specifically, the revised label noted that "compulsive behaviors (including sexual [behaviors] and pathological gambling)" had been observed as an adverse reaction in Mirapex patients during post-approval use. (Exh.L.) The update was effective immediately, and the additional information appeared in print beginning in March 2005. (Exh.M.) The revised warnings are adequate as a matter of law. Therefore, plaintiffs cannot base any recovery on an alleged failure to warn after November 2004.

F. Plaintiffs Zwayer's and Dodd's Claims Fail For Other Reasons Unique To Their States' Laws

1. Zwayer's Failure To Warn Claims Fail Under Florida's Learned Intermediary Rule Because There Is No Evidence That A Different Warning Would Have Influenced His Physician

Under Florida's learned intermediary doctrine, "the manufacturer's duty to warn runs to the physician, not the patient." *Beal v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007). "[A] plaintiff must not only show that a manufacturer's warning was inadequate, but that such inadequacy affected the prescribing physician's use of the product and thereby injured the plaintiff." *Baker v. Danek Med., Inc.*, 35 F. Supp. 2d 875, 881 (N.D. Fla. 1998); *see also Alexander v. Danek Med., Inc.*, 37 F. Supp. 2d 1346, 1350 (M.D. Fla. 1999) (granting summary judgment to pharmaceutical defendant because

"[p]laintiff cannot show that the inadequacy of the manufacturer's warning affected [the physician's] use of the product").

In states, such as Florida, that have never adopted a rebuttable presumption that a prescribing physician would have heeded an adequate warning if given, the plaintiff "bears the full burden of proving through affirmative evidence that the inadequate warning was the proximate cause of the injury, or, in other words, that an adequate warning to the prescribing physician would have altered the physician's conduct." *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001) (granting summary judgment for drug manufacturer where neither party asked plaintiff's physician whether issuance of plaintiff's proposed warning would have changed the physician's prescribing decision).

Zwayer alleges that he gambled compulsively because of Mirapex from August or September 2004 to July 2005. (Exh.CC at 122, 143-44; Exh.HH at 115-17.) Up until April 2005 (*i.e.*, for most of the period that he was on Mirapex), Zwayer was treated by Dr. Hermino Cuervo, the physician who wrote all of Zwayer's Mirapex prescriptions. (Exh.II No. 8; Exh.JJ at 28, 55, 60.) Zwayer has offered no evidence that Dr. Cuervo would have changed his prescribing practices had the Mirapex label contained a warning of pathological gambling at the time. Zwayer has not even disclosed what an alternate warning would have said. *See Jaurequi v. Carter Mfg. Co.*, 173 F.3d 1076, 1084 (8th Cir. 1999) (affirming summary judgment where plaintiffs' experts had neither designed alternate warnings nor tested their effectiveness, rendering opinions "extremely questionable.").

As a result, Zwayer, as a matter of law, cannot establish causation with respect to his failure-to-warn-related claims.[3] BIPI and Pfizer are therefore entitled to summary judgment on all of those claims up until April 2005.

2. Dodd's Failure To Warn Claims Fail Under Texas' Learned Intermediary Rule Because His Physician Knew About Reports Of Pathological Gambling In Mirapex Patients Yet Instructed Dodd To Continue Taking The Drug

Texas also applies the learned intermediary doctrine in prescription drug cases. *See, e.g., Wyeth-Ayerst Labs. v. Medrano*, 28 S.W.3d 87, 91 (Tex. App. 2000); *Stewart v. Janssen Pharms.*, 780 S.W.2d 910 (Tex. App. 1989); *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (applying Texas law). Under that doctrine, "even if . . . the plaintiff can prove that the given warnings were inadequate, the plaintiff still must prove causation." *Medrano*, 28 S.W.2d at 95 (emphasis added). In other words, a plaintiff must show that the inadequate warning "was the producing cause of the plaintiff's injury." *Id.* at 94. In order to meet this burden, "the plaintiff must show that a proper warning would have changed the decision of the intermediary to prescribe the product." *Brumley*, 149 F. Supp. 2d at 313; *Medrano*, 28 S.W.2d at 96 (same).

A plaintiff cannot meet this burden if his or her prescribing physician testifies that an allegedly adequate warning would not have changed the physician's decision to prescribe the product. *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 555-56 (N.D. Tex. 2006) (plaintiff could not meet his burden under the learned intermediary doctrine because prescribing physician testified that a different warning would not have changed

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[3] In Florida, the learned intermediary doctrine applies to all claims arising out of a manufacturer's failure to warn, regardless of the title the plaintiff puts on each of those claims. *Beal*, 492 F. Supp. 2d at 1372-73.

his prescribing decision); *Gerber v. Hoffman-La Roche, Inc.*, 392 F. Supp. 2d 907, 921 (S.D. Tex. 2005) (same); *Medrano*, 28 S.W.2d at 96 (same).

Here, Dodd's physician, Dr. Farmer, testified that ***even if*** the Mirapex label had contained information about a risk of a possible connection between Mirapex and pathological gambling at the time he prescribed Mirapex to Dodd, he would not have done anything differently. (Exh.KK at 67.) Indeed, even though the precaution section of the current Mirapex label states that cases of pathological gambling have been reported by patients on Mirapex and that such behavior has generally been reversible upon dose reduction or treatment discontinuation [Exh.O at 1859135], Dr. Farmer does not currently warn his Mirapex patients about a risk of pathological gambling. He continues to give the same advice he has always given to his Mirapex patients (including Dodd) – to be alert to changes in their behavior. (Exh.KK at 113-15.)

Because a stronger warning indisputably would not have altered Dr. Farmer's decision to prescribe Mirapex, Dodd cannot prove claims based on an alleged failure to warn.[4] BIPI and Pfizer are therefore entitled to judgment on each of those claims.

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[4] As in Florida, the Texas learned intermediary doctrine bars all claims based on an alleged failure to warn, no matter how described or labeled in the complaint. *Koenig*, 435 F. Supp. 2d at 554-55 (learned intermediary doctrine barred claims for strict liability, breach of implied warranty of merchantability, negligence, and misrepresentation); *In Re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. at 709 (under Texas law, where gravamen of plaintiffs' causes of action for strict liability, negligence, misrepresentation, and breach of implied warranty was that defendant failed to adequately warn of medication's "side effects," the learned intermediary doctrine applied to all claims).

3. Dodd Cannot Prevail On His Failure-To-Warn Claims Against BIPI Or Pfizer Because The FDA-Approved Warnings For Mirapex Are Presumptively Adequate Under Texas Law

Texas law presumes, subject to limited exceptions not applicable here, that FDA-approved pharmaceutical warnings are adequate as a matter of law. Mirapex's warnings were at all times FDA approved.

a. Defendants Are Entitled To The Presumption That The FDA-Approved Warnings Are Adequate In The Dodd Case

Under Texas law, an FDA-approved warning on a pharmaceutical product is presumed to be adequate unless the plaintiff can satisfy certain narrow exceptions. Tex. Civ. Prac. & Rem. Code Ann. § 82.007. The statute provides:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings for information with regard to a pharmaceutical product, ***there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information*** if:
>
> (1) the warnings or information that has accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301, et seq.), as amended or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended.

Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a) (applicable to cases filed after September 1, 2003) (emphasis added).

The Texas legislature enacted this provision to ensure that state courts do not second guess the extensive FDA review process. *See, e.g.*, Debate on House Bill 4 on the Floor of the House of Representatives, 78th Leg., R.S. 74-75 (March 27, 2003) ("[T]he intent of this section is to say this: if a pharmaceutical product has gone through . . . the

rigorous review and approval process, and that approval process established a certain set of warnings that need[s] to be given . . ., and if a manufacturer or retailer uses that exact warning . . ., then [it] cannot be held liable for . . . marketing defects for failure to give the proper warning.").

Here, all of the warnings accompanying Mirapex were approved by the FDA following the FDA's rigorous process. (Exhs.H,J.) As a result, and as a matter of law, defendants are entitled to the presumption that the warnings accompanying Mirapex were adequate.

b. Dodd Cannot Overcome the Statutory Presumption of Adequate Warnings Because The Exception That He Will Invoke Is Preempted By Federal Law

The Texas statute provides five narrow exceptions to the presumption of adequate warnings, including one that Dodd likely will attempt to invoke – that defendants engaged in fraud on the FDA by failing to provide required information. Tex. Prac. & Rem. Code Ann. § 82.007(b)(1). That exception is unavailable because any claim that defendants either misrepresented or did not provide the FDA with required information about Mirapex is preempted by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, and its implementing regulations (collectively "FDCA").

In *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 355 (2001), the U.S. Supreme Court held that state-law "fraud-on-the-FDA" claims are preempted by the FDCA and its implementing regulations, because the FDCA provides that "all . . . proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States." 21 U.S.C. §337(a) (emphasis added). As the Supreme Court explained in *Buckman*, that enforcement provision creates a comprehensive

regulatory scheme under which the FDA has exclusive authority to enforce compliance with the provisions of the Act. *Id.* at 348-49. For this reason, state law "fraud-on-the-FDA" claims thus "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. Similarly, permitting civil litigation over alleged "frauds" or "violations" that the FDA itself never deemed to exist or never found worthy of action would subvert the FDA's preeminent role in the regulatory scheme. *Id.*

Several courts interpreting *Buckman* in the context of similar statutes have ruled that *Buckman* preempts "fraud-on-the-FDA" exceptions like the one in the Texas statute, absent an FDA finding that fraud was committed. For example, in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965-66 (6th Cir. 2004), the Sixth Circuit held that a plaintiff may proceed under the "fraud-on-the-FDA" exception to Michigan's analogous FDA immunity statute only where "the FDA itself determines that a fraud has been committed on the agency during the regulatory-approval process." *Id.* at 966. In reaching this conclusion, the *Garcia* court found that allowing a plaintiff to seek refuge in the statute's exception by arguing fraud on the FDA "would raise the same inter-branch-meddling concerns that animated *Buckman*." *Id.* at 966.

Indeed, earlier this year, a Texas state court ruled that the Texas statute was preempted under the Supreme Court's *Buckman* ruling. *See Ledbetter v. Merck & Co.*, No. 2005-59499, 2007 WL 1181991 (Tex. Dist. Apr. 19, 2007). In that case, the Texas court cited the same federalism concerns that drove *Buckman* and observed,

> Under the Texas Act, in order to pursue a failure to warn case, plaintiffs must prove that required and material information was withheld from the FDA. Whether it is an element of the plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same. All of the federalism concerns in *Buckman* still apply. The requisite showing under the Texas Act is analogous to and sufficiently equivalent to plaintiffs

> asserting a claim on fraud on the FDA that the claim is preempted under *Buckman*.

Id. § II.C. Other courts have reached similar conclusions with regard to similar statutory provisions. *See, e.g.*, *Henderson v. Merck & Co.*, No. 04-CV-05987 LD, 2005 WL 2600220, at *11 (E.D. Pa. Oct. 11, 2005) (holding that fraud-on-the-FDA exception is preempted, absent an FDA finding of fraud); *Kobar v. Novartis Corp.*, 378 F.Supp.2d 1166, 1172-74 (D. Ariz. 2005) (concluding that language in Arizona's punitive damages statute similar to the Texas fraud-on-the-FDA exception is preempted by federal law).[5]

The Texas fraud-on-the-FDA exception necessarily implicates second-guessing the FDA on whether defendants failed to provide information. The FDA has never found that defendants engaged in any fraud against the agency, nor has the FDA ever faulted or criticized BIPI or Pfizer in connection with Mirapex. As a result, Dodd cannot invoke this exception, and any effort to claim that the FDA was defrauded is preempted. The Texas statute therefore bars all of Dodd's claims based on an alleged failure to warn.

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[5] Dodd will claim that these cases are distinguishable because he has made traditional state law tort claims and not a claim of fraud-on-the-FDA. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94-96 (2d Cir. 2006) (finding that Michigan statute was not preempted under *Buckman* because *Buckman* applied only to fraud-on-the-FDA claims and not traditional state law claims), *cert. granted sub. nom., Warner-Lambert Co. v. Kent*, et. al., No. 06-1498, 2007 WL 1420397 (U.S. Sept. 25, 2007); *see also Ackermann v. Wyeth Pharmaceuticals*, 471 F. Supp. 2d 739, 748-50 (E.D. Tex. 2006) (denying summary judgment, reasoning that the Texas fraud-on-the-FDA exception did not "create a cause of action where none existed before"). However, this Court has characterized claims made in identical complaints as fraud-on-the-FDA claims. Moreover, the *Ledbetter* order quoted above explains that casting fraud-on-the-FDA claims in common law terms does not avoid federal preemption.

G. If Plaintiffs Are Alleging Manufacturing Defect And Design Defect Claims, Those Claims Also Fail

All indications are that plaintiffs are pursuing their product liability claims based only on an alleged failure to warn. To the extent, however, they allege claims based on a manufacturing defect or a design defect, there is no evidence to support those claims.

It is not clear that plaintiffs have alleged manufacturing and design defect claims at all. Their Complaints include no separately pleaded manufacturing or design defect claims. Instead, in their first cause of action for strict liability, plaintiffs allude to a defect "in design or formulation" together with their allegations that defendants failed to warn. (*See* Complaints ¶¶ 24-25.) The Complaints' more specific factual allegations do not elaborate on a manufacturing or design defect theory.

More importantly, if plaintiffs are pursuing manufacturing and design defect claims, there is no evidence to support them. There is no evidence that the Mirapex ingested by any plaintiff deviated in any way from the intended design of the drug. *See, e.g.*, *Gerber*, 392 F. Supp. 2d at 922 ("A manufacturing defect exists when a product does not conform to the design standards and blueprints of the manufacturer . . . ."); *Harduvel v. General Dynamics Corp.*, 801 F. Supp. 597, 606 n.16 (M.D. Fla. 1992) (manufacturing defect exists if the product "fail[s] to conform to specifications").

There likewise is no evidence that Mirapex's design is defective, that it should have been designed differently, or that it should no longer be prescribed to treat PD. *See Gerber*, 392 F. Supp. 2d at 922 (plaintiff asserting a design defect "must demonstrate that the defendant could have provided a safer alternative design") (citing *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 335 (Tex. 1998)); *Husky Indus. v. Black*, 434 So.

2d 988, 991 (Fla. Dist. Ct. App. 1983) (a "defectively designed product is one that has been negligently designed"); *Green v. Smith & Nephew AHP, Inc.*, 245 Wis. 2d 772, 823 n.17 (2001) (design defect cases are cases "in which the product at issue conforms with its intended design, but the design itself allegedly is defective"). Again, plaintiffs have offered no evidence that Mirapex could have been designed in a safer manner. None of plaintiffs' experts has opined that the Mirapex ingested by plaintiffs was defective in design or manufacturing, and none of plaintiffs' expert witnesses has testified that Mirapex should be removed from the market.

Plaintiffs' manufacturing and design defect claims – if plaintiffs are pursuing them at all – are afterthoughts. There is no evidence to support either claim, and Pfizer and BIPI are entitled to summary judgment on both.

H. Plaintiffs Are Not Entitled To Punitive Damages Claims In These Cases

Plaintiffs' punitive damages claims are premised on allegations that BIPI and Pfizer failed to provide the FDA with information regarding the purported association between Mirapex and pathological gambling. (*See* Memorandum of Law in Support of Plaintiffs' Motion to Amend Complaint to Add Claims for Punitive Damages at 13 (arguing that if Defendants had coded adverse events in its reports to the FDA differently in the 1990s, the FDA would have been alerted to a side effect); *id.* at 15 (arguing that if Defendants had sent the 2000 Stacy Abstract to the FDA in 2000, the FDA would have required a label change); *id.* at 32 ("Had these events been properly reported to the FDA, a very strong 'signal' for gambling would have been found in 2000."); *id.* at 33 (asserting

that BIPI's failure to provide the FDA with the BI Germany Clinical Expert Statement, "prevented the FDA from doing its job.").)[6]

In other cases filed in this MDL proceeding, this Court has determined that allegations such as these amount to a claim of "fraud on the FDA." (*See* 11/26/07 Order at 7-8.) However, as explained immediately above, the Supreme Court has ruled that claims of fraud-on-the-FDA are preempted by federal law. *Buckman*, 531 U.S. at 348. As a result, plaintiffs' claims that defendants' dealings with the FDA warrant punitive damages are preempted under federal law.

IV

CONCLUSION

For the reasons stated above, Pfizer and BIPI are entitled to summary judgment on all plaintiffs' claims, including the spousal loss of consortium claims, as set forth in the defendants' notice of motion.

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6 Of course, all this information was eventually reported to the FDA, and the FDA did *not* request a label change. This underscores how contrived and meritless plaintiffs' claims are.

Dated: January 22, 2008.

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